

REMARKS

35 USC §103(a)

The rejection of claims 1-10, 12-16 and 18-21 under 35 U.S.C. §103(a) as being unpatentable over Wheeler (WO 97/32559) in view of the Clariant product brochure has been maintained. The rejection states:

Wheeler teaches the preparation of bi-liquid foam by combining oil-based biliquid foam and an aqueous gel, CARBOPOL gelling polymer and the pH is adjusted to 6.5 with citric acid (page 6, lines 1-10 and 20-23 and example 3).

Wheeler teaches cosmetic or pharmaceutical composition comprising a stable dispersion that comprises oil-based bi-liquid foam and an aqueous gel. The oil-based bi-liquid foam of Wheeler is from 1% to 80% by weight of the total formulation. The composition of Wheeler also comprises silicones oils wherein the oils can be cyclomethicone, dimethicone, dimethicone copolyol, lanolin and dimethiconol. Wheeler teaches a formulation further comprising from 0.05% to 0.5% of surfactant and active ingredient in the aqueous or oily phase. Wheeler teaches that the low level of surfactant incorporated into the formulation comprises quaternary ammonium sulfonium salts, amphoteric surfactant, anionic surfactant, alpha-olefin sulfonate, and ester-linked sulfonate. Salts of cross-linked polymers of acrylic acid (carbomers), glyceryl polymethacrylates, or copolymers of polyoxyethylene/polyoxypropylene in mixtures with the previously listed surfactants may serve as gelling agents. Wheeler's composition (example 3) comprises Citric acid at 1% (Example 2) and the composition is adjusted to pH 6.5 (less than pH 7). See page 3, paragraph 2 to page 5 paragraph 2. The 1% of the hydroxyl acid in Example 2 meets the salt requirement in claims 1, 3-5.

Regarding the percent amounts of the gallant and the salt, it would be obvious to use appropriate amount of the gallant to effect the desired viscosity of the gelled composition. However, Wheeler does not use polymeric sulfonic acid as a gelling agent. However, Clariant product brochure teaches Aristoflex AVC or copolymer of polyacryldimethyltauramide and vinylformamide gelling agent for aqueous systems and thickening agent for oil-in-water emulsions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the bi-liquid foam by gelling the composition with CARBOMER polymer according to the teachings of Wheeler. One having ordinary skill in the art would have been motivated to substitute CARBOMER gelling agent with another gelling agent such as polyacryldimethyltauramide-co-vinylformamide (Aristoflex) with the expectation that the aqueous composition will be gelled.

The rejection is again respectfully traversed. Once again, prior to addressing the merits of the rejection, the Applicants wish to restate the nature of the present invention.

The instant invention provides an improved aqueous gel formulation that can be used to deliver the necessary therapeutic agents while retaining the stability and the elegant texture of a gel product. The composition comprises an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase having a pH of less than 7 (i.e. acidic) and comprising a polymeric sulfonic acid gellant. The otherwise unstable biliquid foam is stabilized in the presence of the aqueous gel containing the polymeric sulfonic acid gellant and very little surfactant. Unlike known compositions of similar utility, the claimed invention utilizes a polymeric sulfonic acid gelling agent which surprisingly and unexpectedly can be used in the presence of substantial amounts of electrolytes in an aqueous phase having a pH of less than 7 (i.e. an acid pH) without undesirable effects on the texture of the gel.

It is the Examiner's position that Wheeler discloses the Applicants' invention except for the polymeric sulfonic acid gellant, but that the Clariant brochure teaches the use of a polymeric sulfonic acid gellant in low pH formulations of the type disclosed in Wheeler, such that it would have been obvious to a person of ordinary skill in the art to substitute the gellant in Clariant for the gellants disclosed in Wheeler to arrive at the Applicants' invention.

Turning first to Wheeler, the Applicants acknowledge that the reference discloses compositions containing a biliquid foam, the foam containing very small amounts of surfactant (see example 1 in which the biliquid foam contains a total of 0.95% surfactants – polyoxyethylene lauryl ether and lauryl betaine). Nevertheless, in addition to the lack of any disclosure or suggestion in the reference to use a polymeric sulfonic acid gellant, the reference also fails to disclose a formulation in which the salt-containing aqueous phase has a pH of less than 7, and, wherein the total formulation comprises less than 1% by weight of surfactant. Examples 2 and 3 of the reference are the sole formulations disclosed as having a pH less than 7. However, these formulations each contain over 20 weight percent surfactants. The surfactants, in addition to the surfactants in the biliquid foam, include ammonium lauryl sulphate, ammonium lauryl ether sulphate, cocamidopropyl betaine, coconut diethanolamide and cetostearyl alcohol. The amount of the aqueous ammonium lauryl sulphate alone in each of the example 2 and 3 formulations is 13.5% (.33 x 41). As disclosed in the reference at page 5, line 27 – page 6, line 10, shampoos and shower gels generally contain 4-18% by

weight of a primary surfactant and 2-15% by weight of a coactive surfactant. It is disclosed in particular on page 5, lines 7-10 that "It is clear from the above description that by the nature of the conventional formulations this kind of dispersion contains a higher proportion of surfactant than those previously described as features of the invention." In fact, it is well known that, particularly in shampoos, surfactants are the primary cleansing agent and that surfactants are selected based on proper detergency without degreasing (cleaning without removing too much oil from the hair), ability to form delicate and rich bubbling, easy rinsing, good finish after washing hair, minimal skin/eye irritation, no damage to hair, low toxicity and good biodegradability. Generally, the higher alcohol type-anion surfactant provides the proper detergency and forms rich bubbles, and a non-ionic surfactant is added as coadjuvant. Additionally, the proper balance of surfactants provides a shampoo with a slightly acidic pH of about 5.5 - 6.5, since a basic environment weakens the hair by breaking the disulfide bonds in hair keratin. Citric acid is typically used to provide the desired pH. The cuticle of the hair, which is exposed after the sebum is stripped away, is covered with overlapping scales that are smoothed and soothed in a properly acidic environment. Aggravated scales don't overlap nicely, and they make hair look dull and feel rough. They can also snag other raised scales on neighboring shafts, resulting in snarls. Therefore, the Wheeler reference teaches away from using less than 1% surfactant in the biliquid-containing formulations of examples 2 and 3 having an aqueous phase of pH less than 7. That an Applicant acts contrary to the teachings of the prior art is strong evidence of nonobviousness. *In re Hedges*, 228 USPQ 685 (Fed. Cir. 1986).

In contrast to the Examiner's analysis of the teachings of the disclosure in the Clariant brochure, the Applicants submit again that the brochure does not provide any teaching to compensate for the defects of the disclosure of Wheeler as it relates to the presently claimed formulations. The Clariant brochure merely discloses that the polymeric sulfonic acids of the present invention are known in the art for use as a gellant of an aqueous phase of an emulsion. Therefore, even though it also is disclosed that the gellant may be used under low pH conditions, there is absolutely no disclosure or suggestion to use the polymeric sulfonic acids in formulations of the type disclosed in Wheeler, i.e., dispersions containing a biliquid foam and aqueous gel. As explicitly disclosed in Wheeler (page 3, lines 3-6), "These foams are not emulsions...They are insufficiently stable to form usable cosmetic or pharmaceutical products..." Therefore,

the Examiner's reasoning that the "Clariant product brochure teaches polymer sulfonic acid as gelling agent for systems such as the one disclosed by Wheeler and one gelling agent can be substituted for another and expect the gelling of the aqueous solution to take place" is entirely unsupportable. While it may arguably be obvious to try to use the Clariant gellant to gel the aqueous phase of the Applicants' composition, this is not the legal standard by which obviousness is determined; rather, there must be a reasonable expectation of success in achieving the goal. *In re O'Farrell*, 7 USPQ2d 1673 (Fed. Cir. 1988). This cannot be found in the present situation; there is simply no expectation at all with regard to the Clariant product's being able to thicken the biliquid foam dispersion of Wheeler. Therefore, the combination of the Clariant brochure with the disclosure in Wheeler is improper. Given, however, for the sake of argument, that the combination is a proper one, the combination (i.e. biliquid foam dispersions prepared by substituting the polymeric sulfonic acid gellant of Clariant for the conventional gellants disclosed in Wheeler) would still not result in the Applicants' claimed compositions, since the amount of surfactants in the resulting low pH compositions would far exceed 1%. One of ordinary skill in the art, reading the disclosure in Wheeler at page 6, lines 7-10 together with examples 2 and 3, would simply not have been motivated to reduce the total amount of surfactants in the low pH shampoo formulations of examples 2 and 3 in Wheeler. Given the state of the art, there would have been no expectation that the Clariant gellant would have successfully gelled the shampoo formulations in Wheeler in the absence of substantial amounts of surfactants.

For the above reasons alone, the rejection of the claims under 35 USC §103(a) cannot stand. However, the Applicants further submit that the unexpected superiority of the polymeric sulfonic acid in gelling the aqueous dispersions containing biliquid foam in comparison with the carbomer or other gellants disclosed in Wheeler is neither taught nor suggested by either Wheeler or Clariant. As noted in the present specification at page 3, line 26 – page 4, line 6, the gellants recommended for use in Wheeler perform adequately in non-acidic formulations; however, these gellants are incapable of creating a stable dispersions when the aqueous phase to be gelled contains even low levels of electrolytes or salts of desired active ingredients at an acidic pH. The Applicants have previously submitted two declarations which demonstrate that at pH of less than 7, carbomers, as well as other gellants recommended by Wheeler, do not provide a homogeneous and stable product. As discussed above, the Wheeler formulations

wherein the pH is adjusted to less than 7 (examples 2 and 3) contain an enormous quantity of surfactants (greater than 20%) which will counteract any tendency to instability in the use of carbomer as the gellant. In contrast to examples 2 and 3, it is demonstrated in example 4 in Wheeler that, in the absence of large amounts of surfactant, the pH of the moisturizer is adjusted to 7 (by neutralizing with sodium hydroxide). It is abundantly clear that the ability of the claimed gelling agents to stabilize an oil-containing biliquid foam dispersed in a salt-containing aqueous phase having an acidic pH of less than 7, in the absence of large quantities of surfactants, could not have been predicted from the cited references. This result is both surprising and unexpected in view of the teachings of the prior art. This is confirmed in the Harrison declaration previously submitted and discussed again below.

The declarations of Matathia and Harrison unequivocally demonstrate the superiority of the polymeric sulfonic acid in stably gelling the biliquid foam dispersion at pH less than 7. As discussed in the Matathia declaration, various gellants were tested in developing the formulations of the present invention, including the carbomer, but only the polymeric sulfonic acid gellant produced an aesthetically and commercially acceptable product. As further discussed in the Harrison declaration two formulations (derived from Wheeler example 5, which does not include surfactants in addition to the surfactants used in the biliquid foam) were compared. The formulations were adjusted to acidic pH and differed only in the type of gellant used. The results demonstrate that only the formulation using the polymeric sulfonic acid gellant retained its integrity. The traditional gellant recommended in Wheeler did not, in the absence of additional surfactants, produce a stable composition at a pH below 7. Neither Wheeler nor Clariant recognizes that an aqueous composition comprising biliquid foam and electrolytes can be stabilized at acidic pH with less than 1% surfactant in the total composition, the stability of the gel being unaffected by acids when polysulfonic acid gellant is employed. The superiority of the polymeric sulfonic acid gellant in the biliquid-containing dispersions of the present invention is unexpected and not suggested by the references cited. The unexpected results unequivocally rebut any *prima facie* case of obviousness that may be found in combining the Wheeler and Clariant references. ((*In re Soni*, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995). When an applicant demonstrates substantially improved results, as Soni did here, and states that the results were unexpected, this should suffice to establish unexpected results in the absence of

evidence to the contrary.)) Therefore, withdrawal of the rejection of the claims under 35 USC §103(a) is respectfully requested.

Applicants' response to the Examiner's "Response to Arguments"

On page 4 of the office action, in paragraph 5, the Examiner states:

Applicant argues that the composition of Wheeler is a shampoo/shower gel and that less than 1% surfactant cannot be used cleanse the hair, less than pH of 7 is unsuitable for shampoo or shower gel, applicant had provided declaration that the gellants recommended by Wheeler does not provide homogeneous and stable product at pH's of less than 7 and that the sulfonic acid based gelling agents as declared by applicant is superior to the Wheeler gelling agents.

Although it would appear that the Examiner is attempting to restate the Applicants' position, the meaning of the Examiner's statement is not at all clear to the Applicants. The Applicants are not making any claim that shampoo formulations having a pH less than 7 and containing less than 1% surfactants can't be used to cleanse hair. It is the Applicants' position that, given the teachings in Wheeler and the Clariant brochure and the state of the art at the time the present application was filed, one of ordinary skill in the art would not have expected that substituting the polymeric sulfonic acid gellant of Clariant for those disclosed in Wheeler would have resulted in a stable formulation in the absence of greater than 20% surfactants as disclosed in Wheeler examples 2 and 3. Again, the Applicants direct the Examiner to the disclosure in Wheeler in the paragraph common to pages 5 and 6, and particularly at page 6, lines 7-10: "It is clear from the above description that by the nature of the conventional formulations this kind of dispersion contains a higher proportion of surfactant than those previously described as features of the invention." The "features of the invention" referred to in the previous sentence include the use of 0.05 to 0.5%, and preferably between 0.05 and 0.3% surfactants (Wheeler at page 3, lines 19-20). Therefore, the Examiner's statement at the top of page 6 of the office action: "This clearly shows that the percent surfactant is desired to be less than 1%" simply does not follow from, and is obviously based on a misreading by the Examiner of, the disclosure in Wheeler. Additionally, the Examiner's prior statement at page 5, line 16 – page 6, line 2 of the office action: "Although, applicants state that Wheeler's example 3 (page 6) discloses large amount of surfactant in excess of 50%....so that the resultant amount cannot be less than 50%..." is not addressing any argument presented by the undersigned in the

Preliminary Amendment filed with the RCE on November 28, 2006, but appears to have been lifted from an argument of the Examiner in an office action responding to an argument presented by other than the undersigned in an Appeal Brief submitted on October 30, 2003!

The Examiner also states at the top of page 5 of the office action: "The comprising language of the claims is open and does not therefore exclude the other surfactants in the composition of Wheeler." However, the meaning of the Examiner's statement is not clear to the Applicants. The Examiner appears to be addressing an argument made by other than the undersigned in an Appeal Brief submitted on February 28, 2005, before the claims had been amended to require less than 1% surfactant in the total composition. Nevertheless, the present claims require that the compositions comprise "less than about 1 percent surfactant, wherein said weights are by weight of the total composition".

The Examiner also maintains that, as the Clariant product brochure discloses using the polymeric sulfonic acid gellant for thickening aqueous systems and oil-in-water emulsions, the gellant disclosed in the Clariant brochure would be expected to successfully gel or thicken the composition of Wheeler. This assertion by the Examiner is not new and has been addressed above by the Applicants. Nevertheless, Applicants' again summarize their position here. The Clariant brochure discloses that the polymeric sulfonic acid gellants can be used in low pH formulations: that is, in the low pH aqueous phase of emulsions. There is no disclosure or suggestion in Clariant to use the gellants in the formulations disclosed in Wheeler which formulations are dispersions containing a biliquid foam and aqueous gel. Given, however, only for the sake of argument, that the combination of the teachings of Clariant and Wheeler is a proper one, the formulations resulting from the combination would not be the Applicants' claimed compositions, since the amount of surfactants in the resulting low pH compositions would far exceed 1%. Wheeler's examples 2 and 3 for shampoo compositions are the sole low pH compositions disclosed in that publication and those compositions require significant quantities of surfactants well above the less than 1% in the compositions claimed by the Applicants. Moreover, Wheeler makes it clear that the formulations of examples 2 and 3 contain a higher proportion of surfactants than are described as features of the invention. Therefore, in contrast to the Examiner's position, there can be no expectation

from the disclosures in Wheeler and Clariant that the polymeric sulfonic acid described in Clariant would successfully thicken the dispersions in Wheeler.

The Examiner further states in the middle of page 5 of the office action that: "...applicants' declarations assigning Wheeler as disclosing compositions outside the definition of a biliquid foam appear to give definitions that go against teachings of the prior art and also goes against applicants admission that the WO 97/32559 discloses biliquid foams. The declaration does not provide scientific data disproving the art recognized biliquid foam of Wheeler." Again, it is not clear to the Applicants what point the Examiner is attempting to make. The statement by the Examiner also appears to be addressing an old argument presented in a response to a final office action, submitted on February 28, 2005 by other than the undersigned. The Examiner does not appear to be addressing any argument made by the undersigned in the response accompanying the RCE submitted on December 14, 2006.

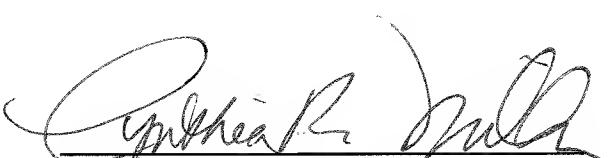
CONCLUSION

The present claims are believed to be in condition for allowance, and prompt issuance of a Notice of Allowance is respectfully solicited. The Examiner is encouraged to contact the undersigned by telephone if it is believed that discussion will resolve any outstanding issues.

Respectfully submitted,

Date:

September 16, 2007



Cynthia R. Miller, Esq., Reg. No. 34,678
Estee Lauder Companies
155 Pinelawn Road
Suite 345 South
Melville, N.Y. 11747
Tel. (631) 414-6068